

AT



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,523	12/17/2001	Ann M. Lees	10797-004004	5012
26161	7590	04/07/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MITRA, RITA	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,523

Applicant(s)

LEES ET AL.

Examiner

Rita Mitra

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 38-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' preliminary amendment filed on December 17, 2001 is acknowledged. Amendment to specification has been entered. Claims 1-37 have been canceled. New claims 38-95 have been added and entered. Therefore claims 38-95 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 38-42, 52-54, 58-61, 71, 73-75, 90, 92 and 94, drawn to an isolated nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence, wherein the polypeptide binds to LDL and at least 80%, or 90% or 95% or 100% identical to the amino acid sequence of SEQ ID NO: 5, or at least 80%, or 90% or 95% identical to a portion of the amino acid sequence of SEQ ID NO: 5, that binds to LDL; an isolated nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence identical to a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO: 5; an isolated nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence, wherein the amino acid sequence binds to LDL and differs by one or more conservative amino acid substitutions from the amino acid sequence of SEQ ID NO: 5 or from the sequence of a fragment of 10 or 20 or 30 amino acid residues of SEQ ID NO:5; a recombinant vector; a cell comprising the recombinant vector; a method of producing polypeptide. Classified in class 536, subclass 23.1, 23.5; class 435, subclass 69.1, 320.1, 252.3, 325, 440, 441.

Should Group I be elected, applicants are required to select SEQ ID NO: 5 from claims 52-54, 71, 73-75.

- II. Claims 43-46, 52-54, 63-66, 71, 73-75, 91, 93 and 95, drawn to an isolated

Art Unit: 1653

nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence, wherein the polypeptide binds to LDL and at least 80%, or 90% or 95% or 100% identical to the amino acid sequence of SEQ ID NO: 8, or at least 80%, or 90% or 95% identical to a portion of the amino acid sequence of SEQ ID NO: 8, that binds to LDL; an isolated nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence identical to a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO: 8; an isolated nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence, wherein the amino acid sequence binds to LDL and differs by one or more conservative amino acid substitutions from the amino acid sequence of SEQ ID NO: 8 or from the sequence of a fragment of 10 or 20 or 30 amino acid residues of SEQ ID NO: 8; a recombinant vector; a cell comprising the recombinant vector; a method of producing polypeptide. Classified in class 536, subclass 23.1, 23.5; class 435, subclass 69.1, 320.1, 252.3, 325, 440, 441.

Should Group II be elected, applicants are required to select SEQ ID NO: 8 from claims 52-54, 71, 74, 75.

-
- III. Claims 47-51, 55-57, 67-70, 72, 76-78, drawn to an isolated nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence, wherein the polypeptide binds to LDL and at least 80%, or 90% or 95% or 100% identical to the amino acid sequence of SEQ ID NO: 44, or at least 80%, or 90% or 95% identical to a portion of the amino acid sequence of SEQ ID NO: 44, that binds to LDL; an isolated nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence identical to a fragment of at least 10 or 20 or 30 amino acid residues of SEQ ID NO: 44; an isolated nucleic acid comprising a nucleotide sequence that encodes a polypeptide comprising an amino acid sequence, wherein the amino acid sequence binds to LDL and differs by one or more conservative amino acid substitutions from the amino acid sequence of SEQ ID NO: 44 or from the

Art Unit: 1653

sequence of a fragment of 10 or 20 or 30 amino acid residues of SEQ ID NO: 44.
Classified in class 536, subclass 23.1, 23.5; class 435, subclass 440, 441.

Should Group III be elected, applicants are required to select SEQ ID NO:
44 from claims 89.

- IV. Claim 62 drawn to an isolated nucleic acid of claim 58, wherein the amino acid sequence comprises SEQ ID NO: 29.
- V. Claim 62 drawn to an isolated nucleic acid of claim 58, wherein the amino acid sequence comprises SEQ ID NO: 41.
- VI. Claims 79-83 drawn to an isolated nucleic acid comprising a nucleotide sequence that specifically hybridizes to the sequence of SEQ ID NO: 14, wherein the nucleotide sequence encodes a polypeptide comprising an amino acid sequence, wherein the polypeptide binds to LDL and at least 80%, or 90% or 95% or 100% identical to the amino acid sequence of SEQ ID NO: 14.
- VII. Claims 79-83 drawn to an isolated nucleic acid comprising a nucleotide sequence that specifically hybridizes to the sequence of SEQ ID NO: 17, wherein the nucleotide sequence encodes a polypeptide comprising an amino acid sequence, wherein the polypeptide binds to LDL and at least 80%, or 90% or 95% or 100% identical to the amino acid sequence of SEQ ID NO: 17.
- VIII. Claims 84-88 drawn to an isolated nucleic acid comprising a nucleotide sequence that specifically hybridizes to the sequence of SEQ ID NO: 46, wherein the nucleotide sequence encodes a polypeptide comprising an amino acid sequence, wherein the polypeptide binds to LDL and at least 80%, or 90% or 95% or 100% identical to the amino acid sequence of SEQ ID NO: 46.
- IX. Claim 89 drawn to an isolated nucleic acid comprising the nucleotide sequence of SEQ ID NO: 40.
- X. Claim 89 drawn to an isolated nucleic acid comprising the nucleotide sequence of

SEQ ID NO: 42.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II/III/IV/V/VI/VII/VIII/IX/X are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions II and III/IV/V/VI/VII/VIII/IX are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions III and IV/V/VI/VII/VIII/IX/X are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions IV and V/VI/VII/VIII/IX/X are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions V and VI/VII/VIII/IX/X are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions VI and VII/VIII/IX/X are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions VII and VIII/IX/X are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions VIII and IX/X are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

Inventions IX and X are related as nucleic acid. However, the nucleic acids differ with respect to their physical, chemical and biological properties. Therefore the inventions are patentably distinct.

The restriction requires for a selection of a single sequence of nucleic acid sequence and the encoded amino acid sequence because each sequence has a different chemical and physical property (See specification pages 8+). For example the polynucleotide sequence encoding the polypeptide having amino acid sequence of human LBP-2 as set forth in SEQ ID NO: 43 (Fig. 7A); while rabbit or human LBP-1 as set forth in SEQ ID NO: 1 (Fig. 1). In addition the invention also includes fragments and variants, which have different amino acid sequences, which are distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Jack Brennan on March 8, 2004, to request an oral election to the above restriction requirement, but did not result in an election being made.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The

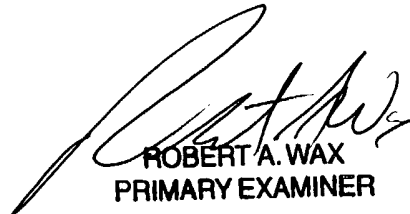
Art Unit: 1653

Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (571) 272-0951. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.

March 30, 2004



ROBERT A. WAX
PRIMARY EXAMINER